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10/801,486	03/16/2004	Riqiang Yan	29915/00281B	9882

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EXAMINER	
BRADLEY, CHRISTINA	

ART UNIT	PAPER NUMBER
1654	

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/801,486	YAN ET AL.	
	Examiner	Art Unit	
	Christina Bradley	1654	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *16 March 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,4-6,14-28,36,41,43,49,52,58-60,63,64,66,70 and 72-83* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1, 4-6, 14-28, 36, 41, 43, 49, 52, 58, 59, 60, 63, 64, 66, 70, and 72-83* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:

I Claims 1, 4-6, 14-28 and 83 drawn to an isolated peptide comprising the sequence $P_3P_2P_1$-$P_1'P_2'P_3'$, classified in class 530, subclass 300.

II. Claims 36, 38 and 41 drawn to a polynucleotide for the expression of the peptides of claim 1, classified in class 536, subclass 22.1.

III. Claims 43, 58-60, 63, 64 and 66 drawn to a method for assaying modulators of □-secretase activity, classified in class 435, subclass 212.

IV. Claim 49, drawn to a method for treating Alzheimer's disease, classified in class 514, subclass 2.

V. Claim 52, drawn to a method for expressing the peptides of claim 1, classified in class 435, subclass 69.1.

VI. Claim70 and 72, drawn to a kit for assaying for inhibitors of □-secretase activity, classified in class 435, subclass 212.

VII. Claims 73-83, drawn to isolated peptides comprising SEQ ID NO: 152, classified in class 530, subclass 300.

2. The inventions are distinct, each from the other because of the following reasons:

3. The DNA of Group II and the polypeptides of Group I are related. The related inventions are distinct if the inventions as claimed do not overlap in scope, i.e., are mutually exclusive; the inventions as claimed are not obvious variants; and the inventions as claimed are either not

capable of use together or can have a materially different design, mode of operation, function, or effect. See MPEP 806.05(j). In the instant case, the DNA claims do not overlap the scope of the polypeptide claims and vice versa as evidenced by the distinct structures and functions of the claimed inventions. A DNA's structure is comprised of linear, contiguous nucleotides while a protein's structure comprised of linear, contiguous amino acids that fold into a specific three-dimensional structure; the DNA's function is to encode a protein while a protein's function is variable, and in this case, to be used as an aspartyl protease substrate. Additionally, the DNA and polypeptides are not obvious variants of each other based on the distinct structures and functions of each as noted above. Lastly, the DNA and polypeptides have materially different functions as noted above. Thus, by virtue of the different structures and functions of the inventions of Groups I and II, these related inventions are distinct.

4. Because these inventions are distinct for the reasons given above and the search required for Group I is not required for Group II, restriction for examination purposes as indicated is proper. To search theses groups together would present a search burden on the Examiner due to the extensive databases of non-patent literature. For example, claims in Group I, drawn to polypeptides, must be searched not only in commercial amino acid sequence databases, but also in textual databases because isolated polypeptides are often disclosed without the benefit of sequence information although the amino acid sequence is inherently the same as the sequence claimed. Additionally, the DNA sequences must be searched in distinct nucleic acid sequence commercial databases. Thus, Groups I and II have been appropriately restricted on the basis of being both independent or distinct and presenting a search burden on the Examiner if they were to be searched together.

5. Inventions I and III are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product. See MPEP § 806.05(h). In the instant case, the peptides of Group I can be used in the materially different process of determining the recognition sequence of an uncharacterized protease.

6. Because these inventions are independent or distinct for the reasons given above and the inventions require a different field of search (see MPEP § 808.02), restriction for examination purposes as indicated is proper.

7. Inventions I and IV are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product. See MPEP § 806.05(h). In the instant case, the process of treating Alzheimer's can be performed using the drug discovered by the method of Group III which utilizes the product of Group I even if the same drug was discovered by another means. Alternatively. Alzheimer's disease can be treated with a drug that was not discovered in the assay which utilizes the peptides of Group I. In addition, the peptides of Group I can be used in the materially different process of determining the recognition sequence for an uncharacterized protease.

8. Because these inventions are independent or distinct for the reasons given above and the inventions require a different field of search (see MPEP § 808.02), restriction for examination purposes as indicated is proper.

9. Inventions I and V are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make another and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case, the products can be made by the materially different process of a solid-phase peptide synthesis.

10. Because these inventions are independent or distinct for the reasons given above and the inventions require a different field of search (see MPEP § 808.02), restriction for examination purposes as indicated is proper.

11. Inventions VI and I are related as combination and subcombination. Inventions in this relationship are distinct if it can be shown that (1) the combination as claimed does not require the particulars of the subcombination as claimed for patentability, and (2) that the subcombination has utility by itself or in other combinations (MPEP § 806.05(c)). In the instant case, the combination as claimed does not require the particulars of the subcombination as claimed because the combination can be formed with any one of the distinct species of Group I. The subcombination has separate utility such as in assays to determine the recognition sequence of an uncharacterized protease.

12. Because these inventions are independent or distinct for the reasons given above and the inventions require a different field of search (see MPEP § 808.02), restriction for examination purposes as indicated is proper.

13. Inventions I and VII are related peptides. The related inventions are distinct if the inventions as claimed do not overlap in scope, i.e., are mutually exclusive; the inventions as claimed are not obvious variants; and the inventions as claimed are either not capable of use together or can have a materially different design, mode of operation, function, or effect. See MPEP § 806.05(j). In the instant case, the peptides of Group I and VII share a common utility (substrates for a human aspartyl protease) but lack a common core structure. Because of their different chemical structures, they do not overlap in scope, are not obvious variants of one another and have a materially different design.

14. Because these inventions are independent or distinct for the reasons given above and the inventions require a different field of search (see MPEP § 808.02), restriction for examination purposes as indicated is proper.

15. Inventions II and III are related. The related inventions are distinct if the inventions as claimed do not overlap in scope, i.e., are mutually exclusive; the inventions as claimed are not obvious variants; and the inventions as claimed are either not capable of use together or can have a materially different design, mode of operation, function, or effect. See MPEP § 806.05(j). In the instant case, Group II is drawn to nucleotides that encode the peptide substrates used in the assay of Group III. Groups II and III do not overlap in scope because the former is drawn to a

chemical compound, a nucleic acid, whereas the latter is drawn to a method for an *in vitro* assay. The product of Group II is not required for the use of the method of Group III as the substrate for the assay could be synthesized by a method not involving expression. Therefore, these inventions are not obvious variants of one another. Furthermore, the inventions have materially different designs.

16. Because these inventions are independent or distinct for the reasons given above and the inventions require a different field of search (see MPEP § 808.02), restriction for examination purposes as indicated is proper.

17. Inventions II and IV are related. The related inventions are distinct if the inventions as claimed do not overlap in scope, i.e., are mutually exclusive; the inventions as claimed are not obvious variants; and the inventions as claimed are either not capable of use together or can have a materially different design, mode of operation, function, or effect. See MPEP § 806.05(j). In the instant case, Group II is drawn to nucleotides that encode the peptide substrates used in the assay to discover the compounds used in the method of Group IV. Groups II and IV do not overlap in scope because the former is drawn to a chemical compound, a nucleic acid, whereas the latter is drawn to a method for treating a disease in a human patient. The product of Group II is not required for the use of the method of Group IV as the substrate for the assay could be synthesized by a method not involving expression and the drug used to treat Alzheimer's could be discovered by another assay. Therefore, these inventions are not obvious variants of one another. Furthermore, the inventions have materially different designs.

18. Because these inventions are independent or distinct for the reasons given above and the inventions require a different field of search (see MPEP § 808.02), restriction for examination purposes as indicated is proper.

19. Inventions II and V are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product. See MPEP § 806.05(h). In the instant case the process for making the peptides could be performed using the materially different products such as the reagents for solid phase chemical synthesis.

20. Because these inventions are independent or distinct for the reasons given above and the inventions require a different field of search (see MPEP § 808.02), restriction for examination purposes as indicated is proper.

21. Inventions II and VI are related. The related inventions are distinct if the inventions as claimed do not overlap in scope, i.e., are mutually exclusive; the inventions as claimed are not obvious variants; and the inventions as claimed are either not capable of use together or can have a materially different design, mode of operation, function, or effect. See MPEP § 806.05(j). In the instant case, Group II is drawn to nucleotides that encode the peptide substrates used in the kit of Group VI. Groups II and VI do not overlap in scope because the former is drawn to a chemical compound, a nucleic acid, whereas the latter is drawn to a kit for an *in vitro* assay comprising an enzyme and peptide substrates. The product of Group II is not required for the

use of the kit of Group VII as the substrate for the assay could be synthesized by a method not involving expression. Therefore, these inventions are not obvious variants of one another. Furthermore, the inventions have materially different designs.

22. Because these inventions are independent or distinct for the reasons given above and the inventions require a different field of search (see MPEP § 808.02), restriction for examination purposes as indicated is proper.

23. The DNA of Group II and the polypeptides of Group VII are related. The related inventions are distinct if the inventions as claimed do not overlap in scope, i.e., are mutually exclusive; the inventions as claimed are not obvious variants; and the inventions as claimed are either not capable of use together or can have a materially different design, mode of operation, function, or effect. See MPEP 806.05(j). In the instant case, the DNA claims do not overlap the scope of the polypeptide claims and vice versa as evidenced by the distinct structures and functions of the claimed inventions. A DNA's structure is comprised of linear, contiguous nucleotides while a protein's structure comprised of linear, contiguous amino acids that fold into a specific three-dimensional structure; the DNA's function is to encode a protein while a protein's function is variable, and in this case, to be used as an aspartyl protease substrate. Additionally, the DNA and polypeptides are not obvious variants of each other based on the distinct structures and functions of each as noted above. Lastly, the DNA and polypeptides have materially different functions as noted above. Thus, by virtue of the different structures and functions of the inventions of Groups II and VII, these related inventions are distinct.

24. Because these inventions are distinct for the reasons given above and the search required for Group II is not required for Group VII, restriction for examination purposes as indicated is proper. To search these Groups together would present a search burden on the Examiner due to the extensive databases of non-patent literature. For example, claims in Group VII, drawn to polypeptides, must be searched not only in commercial amino acid sequence databases, but also in textual databases because isolated polypeptides are often disclosed without the benefit of sequence information although the amino acid sequence is inherently the same as the sequence claimed. Additionally, the DNA sequences must be searched in distinct nucleic acid sequence commercial databases. Thus, Groups II and VII have been appropriately restricted on the basis of being both independent or distinct and presenting a search burden on the Examiner if they were to be searched together.

25. Inventions IV and III are related as combination and subcombination. Inventions in this relationship are distinct if it can be shown that (1) the combination as claimed does not require the particulars of the subcombination as claimed for patentability, and (2) that the subcombination has utility by itself or in other combinations (MPEP § 806.05(c)). In the instant case, the combination as claimed does not require the particulars of the subcombination as claimed because Alzheimer's disease can be treated using the compounds identified in the assay of Group III even if the same compounds were discovered by another method. The subcombination has separate utility such as in determining the recognition sequence for an uncharacterized protease.

26. Because these inventions are independent or distinct for the reasons given above and the inventions require a different field of search (see MPEP § 808.02), restriction for examination purposes as indicated is proper.

27. Inventions III and V are directed to related processes. The related inventions are distinct if the inventions as claimed do not overlap in scope, i.e., are mutually exclusive; the inventions as claimed are not obvious variants; and the inventions as claimed are either not capable of use together or can have a materially different design, mode of operation, function, or effect. See MPEP § 806.05(j). In the instant case, Group V is drawn to a method for making the peptide substrates used in the assay of Group III. Groups V and III do not overlap in scope because the former is drawn to a method for peptide expression, whereas the latter is drawn to a method for an *in vitro* assay. The method of Group V is not required for the use of the method of Group III as the substrate for the assay could be synthesized by a method not involving expression. Therefore, these inventions are not obvious variants of one another. Furthermore, the inventions have materially different effects: expression of a peptide and the identification of an enzyme inhibitor.

28. Because these inventions are independent or distinct for the reasons given above and the inventions require a different field of search (see MPEP § 808.02), restriction for examination purposes as indicated is proper.

29. Inventions VI and III are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the

product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product. See MPEP § 806.05(h). In the instant case, the kit of Group VI can be used in the materially different process of comparing the activity of an unknown protease to that contained in the kit.

30. Because these inventions are independent or distinct for the reasons given above and the inventions require a different field of search (see MPEP § 808.02), restriction for examination purposes as indicated is proper.

31. Inventions VII and III are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product. See MPEP § 806.05(h). In the instant case, the process for using the product as claimed can be practiced with another materially different product such as the peptides of Group I.

32. Because these inventions are independent or distinct for the reasons given above and the inventions require a different field of search (see MPEP § 808.02), restriction for examination purposes as indicated is proper.

33. Inventions IV and V are related. The related inventions are distinct if the inventions as claimed do not overlap in scope, i.e., are mutually exclusive; the inventions as claimed are not obvious variants; and the inventions as claimed are either not capable of use together or can have a materially different design, mode of operation, function, or effect. See MPEP § 806.05(j). In

the instant case, Group V is drawn to a method for making the peptide substrates used in the assay to discover the compounds used in the method of Group IV. Groups V and IV do not overlap in scope because the former is drawn to a method for expression a peptide in cell culture, whereas the latter is drawn to a method for treating a disease in a human patient. The product made by the method of Group V is not required for the use of the method of Group IV as the substrate for the assay could be synthesized by a method not involving expression and the drug used to treat Alzheimer's could be discovered by another assay. Therefore, these inventions are not obvious variants of one another. Furthermore, the inventions have materially different designs.

34. Because these inventions are independent or distinct for the reasons given above and the inventions require a different field of search (see MPEP § 808.02), restriction for examination purposes as indicated is proper.

35. Inventions IV and VI are related. The related inventions are distinct if the inventions as claimed do not overlap in scope, i.e., are mutually exclusive; the inventions as claimed are not obvious variants; and the inventions as claimed are either not capable of use together or can have a materially different design, mode of operation, function, or effect. See MPEP § 806.05(j). In the instant case, Group VI is drawn to a kit used in the assay to discover the compounds used in the method of Group IV. Groups VI and IV do not overlap in scope because the former is drawn to a kit comprising an enzyme and peptide substrates, whereas the latter is drawn to a method for treating a disease in a human patient. The kit of Group VI is not required for the use of the method of Group IV as the drug used to treat Alzheimer's could be discovered by another assay.

Therefore, these inventions are not obvious variants of one another. Furthermore, the inventions have materially different designs.

36. Because these inventions are independent or distinct for the reasons given above and the inventions require a different field of search (see MPEP § 808.02), restriction for examination purposes as indicated is proper.

37. Inventions VII and IV are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product. See MPEP § 806.05(h). In the instant case, the process for using the product as claimed can be practiced with another materially different product such as the peptides of Group I

38. Because these inventions are independent or distinct for the reasons given above and the inventions require a different field of search (see MPEP § 808.02), restriction for examination purposes as indicated is proper.

39. Inventions V and VI are related. The related inventions are distinct if the inventions as claimed do not overlap in scope, i.e., are mutually exclusive; the inventions as claimed are not obvious variants; and the inventions as claimed are either not capable of use together or can have a materially different design, mode of operation, function, or effect. See MPEP § 806.05(j). In the instant case, Group V is drawn to a method for making the peptide substrates used in the kit of Group VI. Groups V and VI do not overlap in scope because the former is drawn to a method

of expressing peptides in cell culture, whereas the latter is drawn to a kit for an *in vitro* assay comprising an enzyme and peptide substrates. The method of Group V is not required for the use of the kit of Group VII as the substrate for the assay could be synthesized by a method not involving expression. Therefore, these inventions are not obvious variants of one another. Furthermore, the inventions have materially different designs.

40. Because these inventions are independent or distinct for the reasons given above and the inventions require a different field of search (see MPEP § 808.02), restriction for examination purposes as indicated is proper.

41. Inventions V and VII are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different designs, modes of operation, and effects (MPEP § 802.01 and § 806.06). In the instant case, Group V is drawn to a method for making peptides other than those included in Group VII. Thus, these inventions do not overlap in scope, are not capable of use together, are not obvious variants, and have materially different designs, nodes of operation and effects.

42. Because these inventions are independent or distinct for the reasons given above and the inventions require a different field of search (see MPEP § 808.02), restriction for examination purposes as indicated is proper.

43. Inventions VI and are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different designs, modes of operation, and effects (MPEP § 802.01 and § 806.06). In the instant case, Group VI is drawn to a kit

comprising peptides other than those included in Group VII. Thus, these inventions do not overlap in scope, are not capable of use together, are not obvious variants, and have materially different designs, nodes of operation and effects.

44. Because these inventions are independent or distinct for the reasons given above and the inventions require a different field of search (see MPEP § 808.02), restriction for examination purposes as indicated is proper.

Election of Species

45. This application contains claims directed to the following patentably distinct species: peptides having the sequence $P_3P_2P_1$-$P_1'P_2'P_3$ including the SEQ ID NO's listed in claim 20. The species are independent or distinct for the reasons below:

46. The sequences of this formula constitute a Markush Group. These sequences share a common utility (cleavage by an aspartyl protease) but do not share a common core structure as none of the variable positions have a fixed amino acid identity. Because of their different chemical structures, these sequences do not overlap in scope, are not obvious variants of one another and have materially different designs.

47. Because these inventions are independent or distinct for the reasons given above and the inventions require a different field of search (see MPEP § 808.02), restriction for examination purposes as indicated is proper.

48. If Groups I-VI are elected, Applicant is required under 35 U.S.C. 121 to elect a single disclosed species (i.e. a SEQ ID NO) for prosecution on the merits to which the claims shall be

restricted if no generic claim is finally held to be allowable. Currently, claims 1, 4-6, 14-28, 36, 38, 41, 43, 49, 52, 58, 59, 60, 63, 64, 66, 70 and 72 are generic.

49. Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

50. Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which depend from or otherwise require all the limitations of an allowable generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

51. This application contains claims directed to the following patentably distinct species: peptides comprising SEQ ID NO: 152. The species are distinct for the following reasons:

52. The peptides comprising SEQ ID NO: 152 constitute a Markush Group. The peptides share a common utility (substrate of an aspartyl protease) and a common structural core (SEQ ID NO:152). However, the fact that the peptides include in this genus can have additional amino acids N- and/or C-terminal to the SEQ ID NO:152 core, renders these compounds related but distinct: because of their different chemical structures, the peptides do not overlap in scope, are not obvious variants of one another and have materially different designs. For this reason, the requirement for an election of species is proper. See § MPEP 803.02.

53. Furthermore these inventions require a different field of search (see MPEP § 808.02). An independent search query for each peptide included in this genus is necessary. To adequately search the patent and non-patent literature databases for each peptide would be a serious burden.

54. If Group VII is elected, Applicant is required under 35 U.S.C. 121 to elect a single disclosed species (i.e. SEQ ID NO) for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claims 74-82 are generic.

55. Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

56. Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which depend from or otherwise require all the limitations of an allowable generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Notice of Possible Rejoinder

57. The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and the product claims are subsequently found allowable, withdrawn process claims that depend from or otherwise require all the limitations of the allowable product claim will be considered for rejoinder. All claims directed a nonelected process invention must require all the limitations of an allowable product claim for that process invention to be rejoined.

58. In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103 and 112. Until all claims to the elected product are found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowable product claim will not be rejoined. See MPEP § 821.04(b). Additionally, in order to retain the right to rejoinder in accordance with the above policy, applicant is advised that the process claims should be amended during prosecution to require the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder**. Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

Conclusion

59. Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species or invention to be examined even though the requirement be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention.

60. The election of an invention or species may be made with or without traverse. To reserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse.

61. Should applicant traverse on the ground that the inventions or species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the inventions or species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C.103(a) of the other invention.

62. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

63. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Christina Bradley whose telephone number is (571) 272-9044. The examiner can normally be reached on Monday through Friday, 8:30 A.M. to 5:00 P.M.

64. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Cecilia Tsang can be reached on (571) 272-0562. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

65. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR

system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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